

CLAIMS

We claim:

1. A system for conducting a plurality of different medical diagnostic tests,
5 the system comprising:

a hand-held portable, self-contained electronic instrument for engaging a
disposable test cell containing a fluid to be tested, the instrument for performing a diagnostic
test selected from said plurality of tests upon the fluid within the test cell, the diagnostic test to
be performed being selected by the instrument based upon identification information obtained
10 from the test cell; and

a disposable, single use test cell for receiving fluid to be diagnostically
tested, the test cell including identification information indicative of a particular diagnostic test
to be performed upon the fluid contained therein, the test cell being sized and shape for
engagement by the instrument.

2. The system as recited in claim 1 wherein the instrument comprises a
housing including an opening for receiving and engaging at least a portion of the test cell
therein.

3. The system as recited in claim 2 wherein the opening in the instrument
housing is sized and shaped for receiving the portion of the test cell with a predetermined
orientation which precludes insertion of the test cell therein with any other orientation.

4. The system as recited in claim 2 wherein the housing includes electrical
25 contacts for engaging corresponding electrical contacts on the test cell when the test cell is
inserted within the opening of the instrument.

5. The system as recited in claim 1 wherein the instrument includes a
processor and a memory, the memory storing data and instructions for the performance of each
30 of the plurality of different diagnostic tests, the processor accessing the memory to obtain data
and instructions for the performance of the selected test based upon the information obtained
from an engaged test cell.

6. The system as recited in claim 1 wherein the test cell includes at least one chamber for receiving fluid to be tested, the chamber containing at least two electrodes for the performance of ion selective analysis on the fluid within the test cell chamber.

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7. The system as recited in claim 6 wherein the test cell further includes a source of calibration fluid for insertion into the chamber for calibration of the electrodes.

8. The system as recited in claim 7 wherein the type of calibration fluid contained within the test cell is determined by the particular test to be performed using the test cell.

9. The system as recited in claim 7 wherein the calibration fluid is inserted into the test cell chamber for calibrating the electrodes before the fluid to be tested is received within the chamber.

10. The system as recited in claim 7 wherein the calibration fluid is inserted into the test cell chamber for calibration of the electrodes after the fluid to be tested is received within the chamber.

11. The system as recited in claim 7 wherein the instrument controls the insertion of the calibration fluid into the test cell chamber.

12. The system as recited in claim 7 wherein the instrument controls the length of time that the calibration fluid remains within the test cell chamber for calibration of the electrodes.

13. The system as recited in claim 6 wherein at least one of the electrodes is covered by an electrolyte, the composition of which is determined by the particular test to be performed utilizing the test cell.

14. The system as recited in claim 13 wherein the electrolyte is in the form of a gel impregnated with a selected ionic material.

15. The system as recited in claim 13 wherein the electrolyte is covered by a ion selective membrane so that the fluid within the chamber to be tested contacts the ion selective membrane.

16. The system as recited in claim 15 wherein the ion selective membrane is comprised of a polymeric material impregnated with chemical species determined by the particular test to be performed utilizing the test cell.

17. The system as recited in claim 6 wherein the electrodes are in electrical contact with the instrument when the test cell is engaged by the instrument.

18. The system as recited in claim 17 wherein the instrument includes electrical circuitry for receiving one of voltage, current and conductivity measurements from the electrodes within the test cell.

19. The system as recited in claim 17 wherein the test cell includes indicia corresponding to the identification information.

20. The system as recited in claim 19 wherein the instrument includes a reader for reading the indicia of the test cell to determine the identification information and for selecting the diagnostic test to be performed.

21. The system as recited in claim 19 wherein the indicia is a barcode on the test cell and wherein the instrument includes a barcode scanner for reading the barcode on the test cell.

22. The system as recited in claim 19 wherein the indicia on a particular test cell is unique to that test cell so that no two test cells contain the exact same indicia.

23. The system as recited in claim 1 wherein the identification information of a particular test cell is unique so that no two test cells contain the same identification information.

5 24. The system as recited in claim 1 wherein the instrument includes a display for displaying the results of diagnostic tests performed by the instrument.

25. The system as recited in claim 24 wherein the display is comprised of a liquid crystal display.

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26. The system as recited in claim 1 wherein the instrument includes an input device to facilitate inputting of information into the instrument.

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27. The system as recited in claim 26 wherein the input device is an alphanumeric keyboard.

28. The system as recited in claim 1 wherein the instrument includes a printer for printing the results of diagnostic tests performed by the instrument.

29. The system as recited in claim 28 wherein the printer comprises a thermal printer.

30. The system as recited in claim 1 wherein the instrument includes an input/output port for communicating with other devices.

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31. The system as recited in claim 30 wherein the input/output port comprises at least one of an RS 232 interface and an Ethernet interface.

32. The system as recited in claim 1 wherein the instrument includes an internal power source.

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33. The system as recited in claim 32 wherein the power source comprises at least one rechargeable battery.

34. The system as recited in claim 33 wherein the instrument further includes a recharger for recharging the at least one rechargeable battery.

35. The system as recited in claim 1 wherein the instrument includes a unique identification code to provide positive identification of all test results obtained using the instrument.

36. The system as recited in claim 6 wherein the instrument compares the conductivity between one pair of electrodes and another reference pair of electrodes.

37. The system as recited in claim 6 wherein the instrument measures current flowing between two electrodes maintained at a controlled voltage potential.

38. The system as recited in claim 11 wherein the instrument includes an actuator which is connected to the test cell when the test cell is inserted into the instrument such that the actuator causes fluid to flow into the test cell chamber.

39. A disposable, single use test cell for receiving a fluid to be diagnostically tested by an instrument, the test cell comprising:

a housing sized and shaped for engagement by the instrument when a diagnostic test is to be performed, the housing including a least one chamber, a first bore in fluid communication with the at least one chamber and a second bore in fluid communication with the at least one chamber;

a pair of electrodes within the at least one chamber for performing ion selective analysis, the electrodes being in electrical contact with circuitry within the instrument when the housing is engaged by the instrument;

a calibration capsule within the first bore, the calibration capsule containing calibration fluid for calibrating the electrodes; and

a specimen capsule within the second bore, the specimen capsule containing the fluid to be tested whereby calibration fluid from the calibration capsule flows from the first bore to the at least one chamber for calibration of the electrodes and the fluid to be tested flows from the specimen capsule through the second bore to the at least one chamber for analysis by the electrodes.

40. The test cell as recited in claim 39 wherein the type of calibration fluid within the calibration capsule is determined by the particular diagnostic test to be performed on the fluid within the specimen capsule.

41. The test cell as recited in claim 39 wherein the calibration fluid flows into the at least one chamber first and is removed from the at least one chamber prior to the fluid from the specimen capsule flowing into the chamber.

42. The test cell as recited in claim 39 wherein at least one of the electrodes is covered by an electrolyte which is determined by the diagnostic test to be performed using the test cell.

43. The test cell as recited in claim 42 wherein the electrolyte is covered by an ion selective membrane so that the calibration fluid and the fluid to be tested contacts the ion selective membrane.

44. The test cell as recited in claim 39 wherein the calibration fluid is caused to flow into the chamber by pushing the calibration capsule into the first bore.

45. The test cell as recited in claim 39 wherein the housing further includes an overflow chamber for receiving fluid to be tested or calibration fluid which overflows the at least one chamber.

46. The test cell as recited in claim 39 wherein the housing further includes identification information which uniquely identifies the test cell.

47. The test cell as recited in claim 46 wherein the identification information also identifies a particular diagnostic test to be performed on the fluid within the test cell.

5 48. The test cell as recited in claim 47 wherein the identification information comprises indicia on the test cell housing.

49. The test cell as recited in claim 48 wherein the indicia comprises a barcode which uniquely identifies the test cell.

10 50. The test cell as recited in claim 39 wherein the housing, calibration capsule and specimen capsule are made of a polymeric material.

51. The test cell as recited in claim 39 wherein the size and shape of the housing permits engagement by the instrument with the housing having only a single, predetermined orientation and precludes engagement by the instrument with the test cell in any other orientation.

52. The test cell as recited in claim 39 wherein the housing includes two chambers, the first and second bores being in fluid communication with both of the chambers, one of the electrodes of the electrode pair being located within one of the chambers and the other electrode of the electrode pair being located within the other chamber.

53. The test cell as recited in claim 52 wherein a diagnostic test is performed by inserting calibration fluid into both chambers and measuring the voltage potential between the electrodes, inserting the fluid to be tested into one of the chambers and measuring the voltage potential between the electrodes and comparing the measured voltage potentials.

54. The test cell as recited in claim 39 wherein the housing includes a single chamber with the electrodes being positioned at spaced locations within the single chamber.

30 55. The test cell as recited in claim 54 wherein a diagnostic test is performed by inserting calibration fluid into the test cell and measuring current flow between the

electrodes, inserting a fluid to be tested into the test cell and measuring current flow between the electrodes and comparing the result of the two current measurements.

56. A disposable, single use test cell for receiving a fluid to be diagnostically tested by an instrument, the test cell comprising:

a housing sized and shaped for engagement by the instrument when a diagnostic test is to be performed, the housing including two elongated chambers of substantially the same dimensions and length and a bore in fluid communication with both chambers;

a first pair of electrodes with each electrode of the first pair being located at an end of one of the chambers, the electrodes of the first pair being in electrical contact with circuitry within the instrument when the housing is engaged by the instrument;

a second pair of electrodes with each of the electrodes of the second pair being located at an end of the other chamber, the electrodes of the second pair being in electrical contact with circuitry within the instrument when the housing is engaged by the instrument; and

a specimen capsule within the bore, the specimen capsule containing the fluid to be tested whereby the fluid to be tested flows from the specimen capsule and into the two chambers, the fluid flowing into one of the chambers being subjected to a lysing agent prior to flowing into the one chamber.

57. The test cell as recited in claim 56 wherein the housing further includes identification information which uniquely identifies the test cell.

58. The test cell as recited in claim 57 wherein the identification information comprises indicia on the test cell housing.

59. The test cell as recited in claim 58 wherein the indicia comprises a barcode which uniquely identified the test cell.

60. The test cell as recited in claim 56 wherein the diagnostic test is performed by measuring the conductivity of the fluid within the one chamber utilizing the first

pair of electrodes, measuring the conductivity of the fluid within the other chamber utilizing the second pair of electrodes and comparing the conductivity measurements.

FIGURE 10